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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
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10/600,130

06/19/2003

John F. Kay

02738.0030.CPUS02

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06/01/2006

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EXAMINER

SILVERMAN, ERIC E

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 06/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                        |                     |  |
|------------------------------|------------------------|---------------------|--|
| <b>Office Action Summary</b> | <b>Application No.</b> | <b>Applicant(s)</b> |  |
|                              | 10/600,130             | KAY ET AL.          |  |
|                              | <b>Examiner</b>        | <b>Art Unit</b>     |  |
|                              | Eric E. Silverman, PhD | 1615                |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-48 is/are pending in the application.
- 4a) Of the above claim(s) 25-40 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 and 41-48 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |   |   |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)             | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)     | Paper No(s)/Mail Date. ____.  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____.   | 6) <input type="checkbox"/> Other: ____.                                    |

### **DETAILED ACTION**

Receipt of response and amendment, filed 5/3/2006, is acknowledged. Claims 1 – 48 are pending, and claims 25 – 40 are withdrawn as drawn to a non-elected invention.

#### ***Response to Arguments***

Applicants' arguments regarding the rejection of claims 1 – 15, 20, 21, 22, 14 – 48 under 35 U.S.C. 103(a) over US 6,309,659 in view of US 6,232,340 have been fully considered and are persuasive. Accordingly, this rejection is **withdrawn**.

Applicants' arguments regarding the rejection of claims 16 – 19 and 22 – 24 under 35 U.S.C. 103(a) over US 6,309,659 in view of US 6,232,340 and in further view of US 5,290,552 have been fully considered and are persuasive. Accordingly, this rejection is **withdrawn**.

Applicants' terminal disclaimer has been received. As such, the double patenting rejection over copending application 10/326,339 is **withdrawn**.

Upon consideration, the following rejections are deemed necessary at this time.

#### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1 – 24 and 41 – 48 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 1 and 41 recite "the sample". It is unclear what "sample" is being referred to, since there are no other recitations of "sample" in those claims. Clarification is requested.

***Claim Rejections - 35 USC § 103***

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1 – 15, 20, 21, 22, 41 – 48 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,309,659 to Clokie in view of US 6,623,729 to Park et al.

Clokie teaches a copolymer that is quite similar the formula of instant claims 1 and 41, wherein the degree of polymerization is commensurate with that recited in claims 5 and 45 (col. 1, lines 45 – 55). The artisan would recognize that the copolymer of Clokie contains hydrophilic and hydrophobic blocks, and that the PEG blocks are the hydrophilic blocks. The difference between the copolymer of Clokie and that of instant claims is that the copolymer of Clokie has PEG blocks with hydroxyl terminated endgroups, whereas the copolymer of instant claims has PEG with methoxy terminated endgroups. Clokie teaches the copolymer in combination with demineralized bone particles, wherein the composition is dispersed in water and exhibits reverse-phase behavior (col.'s 3 and 4). The composition further comprises BMP (col. 3, line 2). The amount of polymer and water is taught to be commensurate with instant claims (claims 3 and 4). Clokie further discloses the composition to contain a therapeutic material, such as osteo-inductive and osteoconductive materials, such as TGF beta types 1 – 13, and bonemorphogenic proteins types 1 – 15 (paragraph bridging col.'s 2 – 3). Other

exemplary materials suggested for inclusion in the composition are gypsum, hydroxyapatite, and calcium salts of phosphate, sulfate, and carbonate. Clokie discloses that the amounts of the components can be varied (paragraph bridging col.'s 4 and 5)

Clokie lacks a teaching of the copolymer with methoxy terminated PEG blocks, and further a teaching of the specific amounts of some of the active agents.

Park teaches block copolymers that comprise hydrophilic and hydrophobic blocks, and that these copolymers can be used to make micelles for delivery of active agents (col. 3, lines 35 – 49, examples 1 and 2). Park teaches that for this application, the PEG blocks are preferably terminated with methoxy endgroups (col. 3, lines 48 – 49).

As such, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to make the composition of Clokie wherein the copolymer has a methoxy terminated endgroup. The motivation to do so comes from Park, who teaches that in block copolymers comprising PEG as the hydrophilic block and another polymer as the hydrophobic block, the PEG should be methoxy terminated, and not hydroxyl terminated, if the artisan desires to achieve sustained release of the active agent. Since such methoxy-terminated PEG copolymers are known in the art, the artisan would enjoy a reasonable expectation of success.

It would be further obvious to a person of ordinary skill in the art at the time of the invention alter the amount of active agents in the composition. This is a matter of dosing, and the artisan would be able to determine the correct dosage of active agents based upon a variety of factors commonly assessed in the art, including nature and

severity of the medical condition, gender, weight, medical history and overall health of the patient, and other factors. The motivation to use the optimal amount of active agents is to effectively treat the patient.

It is noted that claims 1 and 49 specify that the polymer is derived from dilithium salt. However, since the claims are drawn to products, the patentability rests on the nature of the product. As such, Clokie and Park need not teach how the polymer is formed in order to render the claims obvious.

With regard to the claims that require a specific amount of various components, to the extent that Clokie does not disclose these precise amounts or combinations, such is deemed to be obvious. Clokie discloses the physiochemical requirements for the formulation (col. 3 line 65 – col. 5 line 9), and states that the amount of materials may be varied. As such, the artisan would vary the ratio of components in order to achieve a composition having the required physiochemical properties. With regard to the active agents in the composition, such as osteoconductive and osteoinductive agents, the artisan would determine the proper dosage of these materials based on factors routinely dealt with in the art, such as the type and severity of the medical condition being treated, the age, weight, gender, and medical history of the patient, and other factors that the artisan routinely addresses. The motivation is to successfully make the composition of Clokie, and to successfully and effectively treat the patient. Since Clokie states that the proportions of the components can be varied, the artisan would have a reasonable expectation of success.

Claims 16 – 19 and 22 – 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over US 6,309,659 to Clokie, in view of US 6,232,340 to Parks et al. and in further view of US 5,290,552 to Sierra et al.

The teachings of Clokie and Parks are discussed above.

These references do not teach the use of bone chips.

Sierra teaches surgical materials. For dental or orthodontic purposes, Sierra teaches that bone chips are preferably included in combination with bone powder (col. 5, lines 24 – 27).

Thus, it would be prime facie obvious to a person of ordinary skill in the art at the time of the invention to add bone chips to the composition of Clokie and Parks. The motivation to do so comes from Sierra, who teaches bone chips as a preferred ingredient in such compositions, especially when intended for use in dental or orthopedic applications.

### ***Conclusion***

No claims are allowed. No claims are free of the prior art.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eric E. Silverman, PhD whose telephone number is 571 272 5549. The examiner can normally be reached on Monday to Friday 7:30 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on 571 272 8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1615

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



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Art Unit 1615



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